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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,078	07/21/2003	Chris Catalfo	NSI-100RCA	5990

7590 02/03/2006

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EXAMINER

HAWES, PILI ASABI

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 02/03/2006



Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/624,078	CATALFO ET AL.	
	Examiner	Art Unit	
	Pili A. Hawes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on _____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 19-40 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 19-40 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 04-12-2004.
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Summary

Receipt of the Information Disclosure Statement(s) filed 04-12-2004 is acknowledged. Claims 19-40 are pending in this action. Claims 19-40 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-22, 24, 26, 28, 29, 30, 31-35, 37, 39 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20 and 21 depend from claim 19, which is directed toward a composition comprising minoxidil, saw palmetto extract, nettle root extract, and one or more other ingredients listed in claim 19. Claims 20 recites the limitation, "the topical composition of claim 19, wherein minoxidil comprises about 1 % to about 5%, by weight of the composition". From the language of the claim it is unclear whether the minoxidil comprises 1-5% of the composition or whether the composition comprises 1-5% of the minoxidil. As the Examiner assumes the later interpretation, it is suggested that the word "comprises" be replaced with the phrase "is present in". The same language is present in claim 21, and the same modification is suggested.

Claims 24, 26, 28, 29, 31, 39 are indefinite because these dependent claims depend from themselves.

Claims 32-35 recite the limitation "dietary supplement of claim 31" in the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. These claims depend from claim 31, which is indefinite in that it depends from itself, and which claims particular ingredients for the dietary supplement composition. However the subsequent dependent claims fail to further limit claim 31 because they recite other combinations of ingredients.

Claim 40 recites the limitation "method of claim 39" the first line of the claim. There is insufficient antecedent basis for this limitation in the claim. This claims depends from claim 39, which is indefinite because it depends from itself. Claim 40 also fails to further limit claim 39 because it recites other ingredients.

It is unclear what the terms "bovine extract" and "sulfur" mean in claim 30. Bovine extract comes from a cow. It is unclear as to what particular organ has been extracted. It is unclear whether Applicant intended to imply that elemental sulfur was used in the composition or whether sulfur ions where used.

Claim 37 is indefinite because it depends from itself as well as from claim 31. It is unclear what claim 37 is claiming and to which claim it depends.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

Art Unit: 1615

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27, 28, 30 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Chizick et al. US 5972345.

Chizick teaches a natural formulation for the treatment of hair growth (abstract). The composition is for both oral and topical administration (col. 3, lines 49 and 51) and comprises saw palmetto extract, nettle extract (*Urtica Dioica Extract*), zinc, vitamin B6, and green tea extract (col. 4, lines 50-60). The nettle root extract contains minerals such as iron, magnesium, silica, and sulfur, also vitamins such as B5 or pantothenic acid (col. 3, lines 29-30). Chizick further teaches the addition of African Pygeum extract (col. 3, line 16). The extract comprises ursolic acid (col. 3, lines 18).

Claims 30, 34 rejected under 35 U.S.C. 102(e) as being anticipated by Lam US 6241987.

Lam teaches a dietary supplement comprising nettle root, saw palmetto extract, and pumpkin seeds (abstract and col. 1, lines 10-15).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19-21, 31, 33, 36, 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chizick et al. US 5972345 in view of Nelson US 6149933 and vice versa.

Chizick teaches a natural formulation for the treatment of hair growth (abstract). The composition is for both oral and topical administration (col. 3, lines 49 and 51) and comprises saw palmetto extract, nettle extract (Urtica Dioica Extract), zinc, vitamin B6, and green tea extract (col. 4, lines 50-60). The nettle root extract contains minerals such

as iron, magnesium, silica, and sulfur, also vitamins such as B5 or pantothenic acid (col. 3, lines 29-30).

Chizick does not teach administering the herbal ingredients with minoxidil.

Chizick also does not teach the addition of niacin or fo ti root.

Nelson provides the motivation to combine minoxidil with the natural substances because Nelson teaches that the use of a vasodilator such as minoxidil (topically applied) in combination with the dietary supplement taught by Nelson would increase the effectiveness of each as compared with each used alone (cols. 4 and 5, lines 65-67 and 1-3). Nelson teaches a dietary supplement for hair growth that comprises nettles, pyroxidine, horsetail, niacin, zinc, silica, and Fo-Ti (table 6, cols. 6 and 7).

One of ordinary skill in the art would know how to adjust the amounts of the active ingredients to vary the percentages of each ingredient in the composition.

It would have been obvious to one of ordinary skill in the art to add minoxidil to the topical composition of Chizick because Nelson teaches that the combined administration increases the effectiveness of each. Even though the secondary reference does not teach a topical composition comprising the natural/herbal substances, it would have been obvious to one of ordinary skill in the art to make a topical composition from the ingredients in the composition of Nelson because Chizick teaches that herbal supplement compositions can be administered topically. It would further be obvious since Nelson teaches topically applying minoxidil to the scalp.

It would have been obvious to make a dietary supplement comprising niacin and fo-ti root because Nelson teaches these ingredients are useful in a composition for

promoting hair growth. Thus one of ordinary skill in the art would have been motivated to add fo-ti and niacin to the composition because Nelson teaches its combination with nettle extract, silica, pyroxidine and other vitamins and minerals used by Chizick in the composition for treating hair loss. Thus the addition of the ingredients taught by Nelson to the composition of Chizick would yield a topical or oral composition for the treatment of hair loss, the promotion of hair growth, and the suppression or prevention of hair color loss or graying.

Claims 30, 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson US 6149933 in view of Lam US 6241987 in view of Wheeler US 6197309 and Chizick US 5972345.

Nelson teaches a dietary supplement for hair growth that comprises nettles, pyroxidine, horsetail, niacin, zinc, silica, and Fo-Ti (table 6, cols. 6 and 7).

Nelson does not teach the addition of saw palmetto or pumpkin seed extract to the dietary supplement.

Lam teaches a dietary supplement comprising nettle root, saw palmetto extract, and pumpkin seeds (abstract and col. 1, lines 10-15).

Wheeler teaches that benign prostatic hypertrophy (BHP) leads to increased transformation of testosterone into dihydroxytestosterone (DHT) in the male body (col. 2, lines 1-6).

Chizick teaches that increased levels of DHT are associated with male pattern baldness (col. 1, lines 37-43). The reference teaches that there are reports of men having increased levels of DHT in the scalp in cases of male pattern baldness.

It would have been obvious to one of ordinary skill in the art to make a dietary supplement comprising saw palmetto, pumpkin seed extract, nettle root, niacin, zinc, and fo-ti because it would afford a plurality of benefits such as increased hair growth, suppression or prevention of gray hair, and promotion of prostate gland health.

Claims 19, 20, 22-26, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Niemiec et al. US 6284234.

Niemiec teaches topical compositions for treating hair loss (col. 4, lines 15-17). The reference teaches the topical composition comprises minoxidil and an effective amount of other beneficial agents such as anti-dandruff agents, depilatory agents, and depigmentation agents (col. 4, lines 45-58). Ketoconazole is taught as a preferred beneficial agent for the treatment of dandruff, seborrheic dermatitis and psoriasis (col. 13, line 20 and col. 14, lines 6 and 11). The reference further teaches combining ketoconazole and minoxidil (col. 14, line 31). The reference is further suggestive of using beneficial agents for treating hair loss such as saw palmetto, stinging nettle, pumpkin seeds (col. 16, lines 15-18). The reference further teaches peppermint as a counterirritant (col. 12, line 66), and methyl nicotinate as a suitable analgesic (col. 12, line 59). The reference further teaches glycerin as a pharmaceutically acceptable carrier used to make the topical 2% minoxidil composition (col. 20, lines 35-45). Table 4 discloses a hair growth formulation (col. 27, lines 30-65) that comprises minoxidil and ketoconazole and alcohol and esters.

Even though the reference does not teach isopropyl alcohol specifically it would have been obvious to use it because isopropyl alcohol is rubbing alcohol and is known for use topically as an antiseptic.

Although the reference does not specifically disclose the use of ursolic acid, it does suggest the use of peppermint as a counterirritant. Peppermint is a source of ursolic acid.

It would have been obvious to one of ordinary skill in the art to make a composition for topical administration that comprises minoxidil, saw palmetto, nettle root, and methyl nicotinate from the teaching of the prior art because Niemiec teaches each of these components for a topical composition. It would have been obvious to one of ordinary skill in the art to add pharmaceutically acceptable carriers such as water, glycols, esters, alcohols and lipids, especially glycerine and short chain alcohols, such as ethanol or isopropanol, which are both used topically and have antiseptic properties. It would have been obvious to one of ordinary skill in the art to combine ketoconazole with saw palmetto and nettle root because Niemiec teaches each of these compositions as beneficial agents for use in hair loss treatments. One of ordinary skill in the art would have been motivated to make the combinations of these ingredients as recited in the instant claims to achieve a composition that is useful for treating hair loss. One of ordinary skill could expect a reasonable level of success in relieving, treating or preventing hair loss with the composition of the instant claims because the reference of Niemiec teaches using these specific ingredients to make a topical treatment for the treatment of hair loss.

Note: claims 37, 39 and 40 were not included in the art rejections because the dependency of the claims could not be determined, and therefore a proper search and rejection based on the prior art could not be established.

Cited of Interest

Ursolic Acid, www.ursolicacid.com/botanical.htm- Teaches that peppermint is a source of ursolic acid.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes
Examiner-1615

G.S. Kishore
Gollamudi S. Kishore, PhD
Primary Examiner
Group 1600

Notice of References Cited		Application/Control No. 10/624,078	Applicant(s)/Patent Under Reexamination CATALFO ET AL.	
		Examiner Pili A. Hawes	Art Unit 1615	Page 1 of 1

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	A	US-5,972,345	10-1999	Chizick et al.	424/727
*	B	US-6,241,987	06-2001	Lam, Thanh Kevin	424/727
*	C	US-6,149,933	11-2000	Nelson, Julia A.	424/441
*	D	US-6,284,234	09-2001	Niemiec et al.	424/78.07
	E	US-			
	F	US-			
	G	US-			
	H	US-			
	I	US-			
	J	US-			
	K	US-			
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FOREIGN PATENT DOCUMENTS

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	N					
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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Ursolic Acid, www.ursolicacid.com/botanical.htm -
	V	
	W	
	X	

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APR 12 2004

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	2	3	Attorney Docket Number	10474-002
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U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ³ (if known)			
		3,551,554		Herschler	08-16-1968	
		3,989,816		Rajadhyaksha	11-02-1976	
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		4,082,881		Chen et al.	04-04-1978	
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		5,656,300		Levin	08-12-1997	
		5,183,817		Bazzano	02-02-1993	
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FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁴
		Office ²	Number ²	Kind Code ³ (if known)			
			WO 92/16236	PCT	10-01-1992		
			WO 97/47276	PCT	12-18-1997		
			WO 97/38728	PCT	10-23-1997		
			WO 97/15558	PCT	05-01-1997		
			WO 97/12602	PCT	04-10-1997		
			WO 97/03638	PCT	02-06-1997		
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			WO 95/25500	PCT	09-28-1995		
			WO 95/00495	PCT	01-05-1995		
			EP 0728462 A2	EPO	08-28-1996		
			JP 05286835	JPO	02-11-1993		

Examiner Signature		Date Considered	1-27-2006
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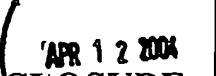
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		Filing Date	7/21/2003
		First Named Inventor	Chris Catalfo et al.
		Group Art Unit	1615
		Examiner Name	
Sheet	2	of	2 3
		Attorney Docket Number	
		10474-002	

U.S. PATENT DOCUMENTS

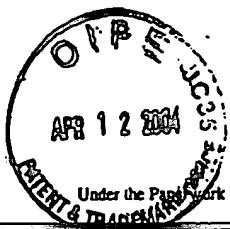
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Substitute for form 1449B/PTO				Complete if Known	
				Application Number	10/624,078
				Filing Date	7/21/2003
				First Named Inventor	Chris Catalfo et al.
				Group Art Unit	1615
				Examiner Name	
Sheet	1	3	of	1	3
				Attorney Docket Number	10474-002

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS		
Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.
		BARRY, B.W. and BENNETT, S.L., "Effect of penetration enhancers on the permeation of mannitol, hydrocortisone and progesterone through human skin", <i>J. Pharm. Pharmacol.</i> , 1987, 53S-546: 39.
		BRODLAND, D.G. and MULLER, S.A., "Androgenetic Alopecia (Common Baldness)", <i>CUTIS</i> , 1991, 173-176:47.
		KATZ, H.I., "Topical Minoxidil: Review of Efficacy", <i>Clinics in Dermatology</i> , 1998, 195-199: 6.
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		SATTAR, A.B. ET AL., "Chemical composition and biological activity of leaf exudates from some Lamiaceae plants", <i>Pharmazie</i> , 1995, 62-65:50.

Examiner Signature	<i>R. Catalfo</i>	Date Considered	1-07-2003
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Ursolic Acid

Introduction
Botanical Sources
Pharmacological Actions of Ursolic Acid
Chemistry
Inhibition of Tumor Promotion in Skin
Hair Growth Stimulant
Toxicity
Antimicrobial Activity
Anti-Aging Agent
Anti-Inflammatory Activity
References
Contact
Home

BOTANICAL SOURCES

Like most triterpenoids, ursolic acid is ubiquitous in the plant kingdom. Ursolic acid and its derivatives are constituents of numerous plants which having diversified phylogenetic origin and taxonomic position. It has been isolated from the protective wax-like coatings of apples, pears, cranberries, prunes, and other fruits⁶. Seaweeds are rich in ursolic acid derivatives. Some of the more commonly known medicinal plants containing ursolic acid are shown in Table 16,7.

Table 1. Partial List of Medicinal Plants Containing Ursolic Acid

Common Name	Botanical Name	Family
Holy Basil (Tulsi)	<i>Ocimum sanctum</i> L.	Lamiaceae
Bilberry	<i>Vaccinium myrtillus</i> L.	Vacciniaceae
Devil's Claw	<i>Harpagophytum procumbens</i> DC	Pedaliaceae
Elder Flowers (European Variety)	<i>Sambucus nigra</i> L.	Caprifoliaceae
Peppermint leaves	<i>Mentha piperita</i> L.	Lamiaceae
Periwinkle	<i>Vinca minor</i> L.	Apocynaceae
Lavender	<i>Lavandula angustifolia</i> Mill.	Lamiaceae
Oregano	<i>Origanum vulgare</i> L.	Lamiaceae
Thyme	<i>Thymus vulgaris</i> L.	Lamiaceae
Hawthorn	<i>Crataegus laevigata</i> (Poir) DC	Rosaceae
Cherry laurel leaves	<i>Prunus laurocerasus</i> L.	Rosaceae

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